

What is claimed is:

1. A method for facilitating the diagnosis of prostate cancer in a subject, comprising:
5 assessing the level of Pin1 in a biological sample from the subject, wherein an elevation in the level of Pin1 is indicative of prostate cancer; and evaluating a TDPCA on the subject such that the diagnosis of prostate cancer is facilitated.
- 10 2. A method for facilitating the diagnosis of prostate cancer in a subject, comprising:
assessing the level of Pin1 in a biological sample from the subject, wherein an elevation in the level of Pin1 is indicative of prostate cancer, and wherein the subject was previously categorized by a TDPCA as being likely to have prostate cancer.
- 15 3. A method for measuring the aggressiveness of prostate cancer in a subject, comprising assessing the level of Pin1 in a biological sample from the subject, wherein an elevation in the level of Pin1 is indicative of the aggressiveness of the prostate cancer.
- 20 4. A method for identifying metastatic prostate cancer in a subject, comprising assessing the level of Pin1 in a biological sample from the subject, wherein an elevation in the level of Pin1 is indicative of metastatic prostate cancer.
- 25 5. The method of claim 1, 2, 3, or 4, wherein assessing the level of Pin1 in a biological sample from the subject comprises contacting the biological sample with an antibody to Pin1 or a fragment thereof; determining the amount of binding of the antibody to the biological sample; and comparing the amount of antibody bound to the biological sample to a predetermined base level.

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6. The method of claim 1 or 2, wherein the subject is receiving, or has received, therapy for a state associated with prostate cancer and the level of Pin1 is indicative of the subject's response to the therapy.
- 5 7. The method of claim 1, 2, 3, or 4, wherein the biological sample comprises a body fluid.
8. The method of claim 7, wherein the body fluid is selected from the group consisting of blood, serum, semen, prostate fluid, seminal fluid, and urine.
- 10 9. The method of claim 5, wherein the antibody is a polyclonal antibody.
10. The method of claim 1, 2, 3, or 4, wherein the biological sample comprises prostate tissue.
- 15 11. The method of claim 5, wherein the antibody is a monoclonal antibody.
12. The method of claim 5, wherein the antibody is a labeled antibody.
- 20 13. The method of claim 12, wherein the amount of binding of the antibody to the biological sample is determined by the intensity of the signal emitted by the labeled antibody.
- 25 14. The method of claim 12, wherein the amount of binding of the antibody to the biological sample is determined by the number cells in the biological sample bound to the labeled antibody.
15. The method of claim 5, wherein the amount of binding of the antibody to the biological sample is determined by a radioimmunoassay.

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16. The method of claim 5, wherein the amount of binding of the antibody to the biological sample is determined by an enzyme immunoassay.
17. A method of diagnosing prostate cancer in a subject, comprising:
 - 5 detecting a level of Pin1 nucleic acid in a biological sample; and
 - comparing the level of Pin1 in the biological sample with a level of Pin1 in a control sample, wherein an elevation in the level of Pin1 in the biological sample compared to the control sample is indicative of prostate cancer.
- 10 18. A method of diagnosing prostate cancer metastasis in a subject, comprising the steps of:
 - 15 detecting a level of Pin1 nucleic acid in a biological sample; and
 - comparing the level of Pin1 in the biological sample with a level of Pin1 in a control sample, wherein an elevation in the level of Pin1 in the biological sample compared to the control sample is indicative of prostate cancer metastasis.
19. The method of claim 17 or 18, wherein the detecting a level of Pin1 nucleic acid in a biological sample comprises amplifying Pin1 RNA.
- 20 20. The method of claim 19, wherein the biological sample is selected from the group consisting of: saliva, sputum, mucus, bone marrow, serum, blood, urine, lymph, tears, semen, seminal fluid, prostate fluid, and prostate tissue.
21. The method of claim 20, wherein the biological sample is a blood sample.
- 25 22. The method of claim 20, wherein the biological sample is a prostate tissue sample.
23. The method of claim 19, wherein the amplifying comprises performing a
30 polymerase chain reaction.

24. The method of claim 1 or 2, wherein the TDPCA is a digital rectal exam showing the subject as having a prostate abnormality.

5 25. The method of claim 1 or 2, wherein the TDPCA is a test for the detection of a prostate cancer marker is selected from the group consisting of: prostatic acid phosphatase, prostate secreted protein, prostate specific membrane antigen, human kallekrein 2, prostate specific transglutaminase, and interleukin 8.

10 26. The method of claim 1 or 2, wherein the TDPCA is a test for the detection of prostate-specific antigen.

27. The method of claim 1 or 2, wherein the TDPCA is a test for the detection of prostate-specific antigen in the blood serum of the subject.

15 28. The method of claim 27, wherein the subject has a blood serum concentration of prostate-specific antigen of between about 2 and about 10 ng/ml.

20 29. The method of claim 27, wherein the subject has a blood serum concentration of the prostate-specific antigen of between about 4 and about 8 ng/ml.

30. The method of claim 27, wherein the subject has a blood serum concentration of the prostate-specific antigen of between about 3 and about 7 ng/ml and the subject is between about 40 and about 60 years old.

25 31. The method of claim 27, wherein the subject has a blood serum concentration of the prostate-specific antigen of between about 5 and about 9 ng/ml and the subject is between about 60 and about 80 years old.

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32. The method of claim 27, wherein the subject has a blood serum concentration of the prostate-specific antigen of less than about 4 ng/ml and a PSA velocity of greater than about 0.7 ng/ml per year.
- 5 33. The method of claim 27, wherein the subject has a blood serum concentration of the prostate-specific antigen of between about 4 and about 8 ng/ml and a percent-free prostate-specific antigen of between about 15 and about 25%.
- 10 34. The method of claim 4, wherein the prostate cancer sample has a Gleason sum of 4-9.
35. The method of claim 34, wherein the Gleason sum is 6 or 7.
- 15 36. A method for determining whether a subject having prostate cancer is likely to respond to treatment comprising a Pin1 inhibitor compound, the method comprising:
assessing the level of Pin1 in a test sample from the subject; and
comparing the level of Pin1 in the test sample to the level of Pin1 in normal tissue, whereby an increased level of Pin1 in the test sample is indicative that the subject is likely to respond to treatment comprising a Pin1 inhibitor compound.
- 20 37. A method of determining if a subject is at risk of developing metastatic prostate cancer comprising:
assessing the level of Pin1 in a test sample from the subject; and
determining if the level of Pin1 in the test sample is indicative of a cancer that
25 will become metastatic.
38. The method of claim 37 wherein the test sample is collected by needle biopsy.
39. The method of claim 37 where the test sample is collected from human serum.

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40. A method of determining if a subject is at risk of developing PSA failure comprising:
- assessing the level of Pin1 in a test sample from the subject; and
- determining if the level of Pin1 in the test sample is indicative of developing PSA failure.

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